

Patent Claims

1. Solid form of an anti-EGFR antibody and/or one of its variants and/or fragments which results in biologically active antibody protein through dissolution or suspension in aqueous medium, obtainable by precipitation of the antibody and/or one of its variants and/or fragments dissolved or suspended in aqueous medium by means of a precipitation reagent.
2. Solid form according to Claim 1, characterised in that use is made of salts, polymers and/or organic solvents as precipitation reagent.
3. Solid form according to Claim 2, characterised in that use is made of ammonium sulfate, sodium acetate, sodium citrate, potassium phosphate, PEG and/or ethanol as precipitation reagent.
4. Solid form according to one of Claims 1 – 3, characterised in that it is a precipitate.
5. Solid form according to one of Claims 1 – 3, characterised in that it is a crystal.
6. Solid form according to one or more of Claims 1 to 5, characterised in that the anti-EGFR antibody is monoclonal and of murine or human origin.
7. Solid form according to Claim 6, characterised in that the anti-EGFR antibody is of murine origin and is chimeric or humanised.
8. Solid form according to Claim 7, characterised in that the anti-EGFR antibody is Mab C225 (cetuximab) or Mab h425 (EMD 72000).

- 5 9. Process for the preparation of a solid form of an anti-EGFR antibody and/or one of its variants and/or fragments which results in biologically active antibody protein through dissolution or suspension in aqueous medium, characterised in that the antibody and/or one of its variants and/or fragments dissolved or suspended in aqueous solution is precipitated by means of a precipitation reagent, and the precipitation product is separated off.
- 10 10. Process according to Claim 9, characterised in that use is made of ammonium sulfate, PEG and/or ethanol as precipitation reagent.
- 15 11. Process according to Claim 9 or 10, characterised in that the process is carried out in batch format.
12. Solid form according to one or more of Claims 1 to 8 as storage-stable medicament.
- 20 13. Pharmaceutical preparation comprising at least one solid form according to one or more of Claims 1 to 8 in precipitated non-crystalline, precipitated crystalline or in soluble or suspended form, and optionally excipients and/or adjuvants and/or further pharmaceutical active ingredients.
- 25 14. Pharmaceutical preparation according to Claim 13, characterised in that the antibody concentration is 10 – 200 mg/ml.
15. Pharmaceutical preparation according to Claim 14, characterised in that the antibody concentration is 50 – 150 mg/ml.
- 30 16. Use of a solid form of an anti-EGFR antibody and/or one of its variants and/or fragments according to one or more of Claims 1 to 8 for

the preparation of a medicine which comprises the biologically active antibody and/or one of its variants and/or fragments in precipitated non-crystalline, precipitated crystalline or in dissolved or suspended form.

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17. Use according to Claim 16 for the preparation of a medicine for the treatment and/or prophylaxis of tumours and/or tumour metastases.

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18. Use according to Claim 17, where the tumour is selected from the group consisting of brain tumour, tumour of the urogenital tract, tumour of the lymphatic system, stomach tumour, laryngeal tumour, monocytic leukaemia, lung adenocarcinoma, small-cell lung carcinoma, pancreatic cancer, glioblastoma and breast carcinoma.

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